

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference  SAL-PB60770	<b>FOR FURTHER ACTION</b>  see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No.  PCT/EP2005/003722	International filing date (day/month/year)  07/04/2005	(Earliest) Priority Date (day/month/year)  09/04/2004
Applicant  SMITHKLINE BEECHAM CORPORATION		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 7 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box II).

3. ☒ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. \_\_\_\_\_

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/EP2005/003722

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/16 A61K9/20 A61K31/426 A61P3/06 A61P3/10  
A61P9/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, WPI Data, PAJ, MEDLINE, EMBASE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96/09056 A (AKZO NOBEL N.V; DE HAAN, PIETER; ZWINKELS, JOCOMINUS, ANTONIUS, MARIA) 28 March 1996 (1996-03-28) page 2, lines 10-19 page 4, lines 25-27 examples I,II,IV,V,VII,VIII,XI	1-15
Y	page 5, lines 15-34	1-15
X	DE 197 14 024 A1 (L.A.B. GESELLSCHAFT FUER PHARMAKOLOGISCHE UNTERSUCHUNGEN MBH & CO., 89) 20 November 1997 (1997-11-20) page 3, lines 5-38	1-15
Y	page 3, lines 32,33	1-15
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Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

\* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*G\* document member of the same patent family

Date of the actual completion of the international search

13 October 2005

Date of mailing of the international search report

24. 10. 2005

Name and mailing address of the ISA

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## INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 97/04750 A (SMITHKLINE BEECHAM PLC; NAPPER, JAMES, ALBERT; MORTIMER, NEIL; O'BRIEN) 13 February 1997 (1997-02-13) cited in the application page 1, lines 7-10 page 3, line 1 - page 4, line 5	1-15
X	MARTINEZ L ET AL: "Active layering and direct compression of sugar spheres: Content homogeneity in low-dosage tablets" PHARMACEUTICAL TECHNOLOGY EUROPE 2001 UNITED KINGDOM, vol. 13, no. 10, 2001, page 38+40+42+44+46, XP009050684 ISSN: 0164-6826 page 40; tables I,II page 45; tables VI,VII page 46: conclusion	1-11, 13-15
X	EP 0 735 864 A (APPLIED ANALYTICAL INDUSTRIES, INC; ENDEAVOR PHARMACEUTICALS) 9 October 1996 (1996-10-09) paragraph '0002! paragraphs '0019!', '0020! paragraphs '0023! - '0025!; example 1	1,5-15
X	WAN LUCY S C ET AL: "Incorporation and distribution of a low dose drug in granules" INTERNATIONAL JOURNAL OF PHARMACEUTICS (AMSTERDAM), vol. 88, no. 1-3, 1992, pages 159-163, XP002336534 ISSN: 0378-5173 page 161; figure 1 page 162; figure 3	1,5-11, 13-15
X	WO 02/096893 A (GLAXO GROUP LIMITED; BOYER, THIERRY; DAY, CAROLINE, JANE; WHITEHEAD, A) 5 December 2002 (2002-12-05) cited in the application page 4, lines 7-13 page 5, lines 1-24 page 11, line 31 - page 12, line 10 page 16, lines 1-13	16-31
X	US 6 518 290 B1 (SIERRA MICHAEL LAWRENCE) 11 February 2003 (2003-02-11) cited in the application column 2, line 29 - column 3, line 25 column 6, line 41 - column 7, line 6 column 9, lines 1-15	16-31

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/EP2005/003722

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: —  
because they relate to subject matter not required to be searched by this Authority, namely:  
Although claims 21-25 and 31 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; It is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-15

Method for preparing ultra low dosage forms with uniform drug distribution  
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2. claims: 16-31

Pharmaceutical composition comprising a specific active compound and its use in the treatment of various diseases.  
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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP2005/003722

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9609056	A	28-03-1996	AT 236639 T	15-04-2003
			AU 700645 B2	14-01-1999
			AU 3608295 A	09-04-1996
			BR 9509019 A	30-12-1997
			CA 2200754 A1	28-03-1996
			CN 1161650 A	08-10-1997
			CZ 9700899 A3	17-09-1997
			DE 69530308 D1	15-05-2003
			DE 69530308 T2	16-10-2003
			DK 782449 T3	04-08-2003
			ES 2196079 T3	16-12-2003
			FI 971172 A	20-03-1997
			HK 1002172 A1	22-08-2003
			HU 77611 A2	29-06-1998
			JP 10505846 T	09-06-1998
			NO 971361 A	21-05-1997
			NZ 293606 A	26-06-1998
			PL 319373 A1	04-08-1997
			PT 782449 T	31-07-2003
			RU 2166936 C2	20-05-2001
			US 5916593 A	29-06-1999
DE 19714024	A1	20-11-1997	AT 243500 T	15-07-2003
			WO 9737638 A2	16-10-1997
			DK 929294 T3	29-09-2003
			EP 0929294 A2	21-07-1999
			ES 2201298 T3	16-03-2004
			PT 929294 T	28-11-2003
WO 9704750	A	13-02-1997	AP 858 A	12-07-2000
			AU 716961 B2	09-03-2000
			AU 6738496 A	26-02-1997
			BG 102266 A	30-10-1998
			BR 9609804 A	06-07-1999
			CA 2228048 A1	13-02-1997
			CN 1196677 A	21-10-1998
			CZ 9800247 A3	17-06-1998
			DZ 2077 A1	22-07-2002
			EA 980179 A1	29-10-1998
			EP 0841902 A2	20-05-1998
			HU 9900521 A2	28-06-1999
			JP 11510493 T	14-09-1999
			MA 23953 A1	01-04-1997
			NO 980384 A	26-03-1998
			NZ 315632 A	29-11-1999
			OA 10659 A	18-09-2002
			PL 325242 A1	06-07-1998
			SK 11098 A3	08-07-1998
			TR 9800156 T1	21-04-1998
EP 0735864	A	09-10-1996	AT 206042 T	15-10-2001
			AU 1515595 A	10-07-1995
			CA 2176461 A1	29-06-1995
			DE 69428455 D1	31-10-2001
			DE 69428455 T2	29-05-2002
			JP 9506899 T	08-07-1997
			WO 9517168 A1	29-06-1995
			ZA 9309565 A	11-08-1994

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP2005/003722

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 02096893	A	05-12-2002	BR 0209892 A	08-06-2004
			CA 2448101 A1	05-12-2002
			CN 1551871 A	01-12-2004
			CZ 20033256 A3	14-04-2004
			EP 1395572 A1	10-03-2004
			HU 0400117 A2	29-03-2005
			JP 2004532265 T	21-10-2004
			MX PA03010943 A	27-02-2004
			NO 20035313 A	09-12-2003
			PL 367114 A1	21-02-2005
			US 2004242657 A1	02-12-2004
			ZA 200308570 A	03-02-2005
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US 6518290	B1	11-02-2003	AT 265442 T	15-05-2004
			AU 758758 B2	27-03-2003
			AU 2003001 A	12-06-2001
			BR 0016067 A	06-08-2002
			CA 2393190 A1	07-06-2001
			CN 1402716 A	12-03-2003
			CZ 20021903 A3	15-01-2003
			DE 60010333 D1	03-06-2004
			DE 60010333 T2	16-06-2005
			DK 1244642 T3	16-08-2004
			WO 0140207 A1	07-06-2001
			EP 1244642 A1	02-10-2002
			ES 2219423 T3	01-12-2004
			HK 1047435 A1	26-11-2004
			HU 0203532 A2	28-02-2003
			JP 2003515597 T	07-05-2003
			MX PA02005456 A	29-11-2002
			NO 20022467 A	26-07-2002
			PL 356772 A1	12-07-2004
			PT 1244642 T	30-09-2004
			TR 200201473 T2	23-09-2002
			TR 200401772 T4	21-09-2004
			TW 555753 B	01-10-2003
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